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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,624	02/04/2002	Roberto Valducci	242/9-1646	4252

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,624

Applicant(s)

VALDUCCI, ROBERTO

Examiner

JOHN D PAK

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9 and 19 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 1-3 and 5-19 are pending in this application.

A new prior art reference has been found and said reference is cited hereinbelow. Further review of the claims in light of the new prior art references necessitates withdrawal of previous indication of allowability of claims 1-2 and 9. In view thereof, the restriction requirement will be maintained, and claims 10-18 stand withdrawn as being directed to non-elected subject matter. Claims 1-3, 5-9 and 19 will presently be examined.

In the event that claims 10-18 should become available for examination on the merits, applicant should take note of the following observations, which are provided now in order to expedite prosecution. Claims 10-18 are directed to process of preparing the formulation of claim 1. This objection is based on the fact that claims 10-18 do not positively recite process steps to ensure preparation of said formulation. The formulation of claim 1 requires lithium salt content of at least 500 mg/g and an in vitro dissolution profile that make it suitable for once-a-day administration. Since claims 10-18 are claimed as process of preparing such a formulation, process steps to provide the 500 mg/g feature and the in vitro dissolution profile must be recited. Additionally, consistent language should be used throughout the claims. Independent claim 1 refers to the inventive granules as "microgranules." Dependent claims should use the same terminology. See

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for example claim 10. In claim 13, "said organic solvent" lacks antecedent basis. In claims 14-15, percentages must be further defined, e.g. percents by weight, volume, moles, etc. In claim 17, the ratio 1:2:9.1 appears incorrect; and the term "amonioethyl" is spelled differently from applicant's evidence in two instances.

Upon further review and reconsideration, claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Dependent claim 2 recites a dosage feature for the formulation of claim 1. However, claim 1 is directed to a formulation per se. As such, the formulation cannot be further defined in terms of a dosage. The dosage is a method feature. The dosage cannot further define what the formulation per se is since it relates to how much of the formulation to take. As a hypothetical example, a bottle of cold syrup is not changed by the fact that a cold sufferer is to take two tablespoons of the syrup. The bottle of cold syrup is unchanged and not further defined by the dose feature, which is a method feature.

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Claims 2, 6, 9 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) In claim 2, "realized with a Lithium salt dosage up to 1000 mg/dose" is unclear and indefinite. It is unclear what is meant by "realized" and it is unclear how the dosage relates to the formulation per se of independent claim 1.

(2) Claim 6, lines 2-3: the term "the modified, release granules" is problematic for two reasons. First, placement of the comma is confusing. It appears that the comma should be deleted. Second, antecedent basis is lacking for the term because independent claim 1 recites "microgranules." Consistency in claim language must be followed.

It is also noted that "metacrylic acid" appears to be a misspelling for --- methacrylic acid --- .

(3) The same "microgranules" and "granules" problem in claim 9 . Independent claim 1 uses the term "microgranules" but dependent claim 9 uses "granules." Consistent terminology should be used.

(4) In claim 19, the percentages must be further defined, e.g. percents by weight, volume, moles, etc.

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The amendment filed on 10/10/03 is objected to under 35 USC 132 because it introduces new matter into the disclosure. 35 USC 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure for the following reasons.

The specification has been amended to recite chemical names for the originally recited trademarks. However, it appears from applicant's own evidence that Eudragit L® was not actually specific enough to necessarily equal to the two substances in the amended specification. It could have meant only the first substance or only the second substance, or any other substance that the manufacturer saw fit to introduce into the market place under the trademark. Applicant's evidence shows that Eudragit L ® is a general term and it is not used by itself to designate a specific substance – it is used in conjunction with other terms, such as Eudragit® L12,5, Eudragit® L 100, Eudragit® L 30, Eudragit® L 30 D-55, and Eudragit® L100-55 (page 1 of 2 of applicant's evidence of 10/10/03). Therefore, without more, "Eudragit L®," as originally recited in claim 17, fails to provide adequate descriptive support for both of the two substances recited in the amended specification.

Applicant is required to cancel the new matter in reply to this Office action.

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For the reasons stated in the above objection to new matter in the specification, claim 7 is rejected under 35 USC 112, first paragraph, as containing subject matter which was not originally described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Furthermore, claim 7 additionally recites "amonioethyl," whereas applicant's own evidence recites --- ammonioethyl --- . Amonioethyl therefore lacks adequate descriptive support from the originally filed disclosure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, 8-9 are rejected under 35 USC 102(b) as being anticipated by Gai et al.

Gai et al. explicitly disclose a formulation of lithium carbonate that contains the following ingredients (p. 133, left column):

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	<u>Hydrophilic formulation</u>	<u>Lipid formulation</u>
Lithium carbonate	300 mg (68.5 wt%)	300 mg (82.2 wt%)
PVP K 30		9.45 mg
Cutina HR (castor oil)		15 mg
Methocel K4MP (HPMC)	120 mg	
Eudragit S100	15.5 mg	
Avicel PH 101		15 mg
Mg stearate	2.2 mg	
Stearic acid		3 mg
Aerosil	0.22 mg	
PEG 4000		22.5 mg

The hydrophilic formulation was granulated with an ethanolic solution of Eudragit S100 and the lipid formulation was granulated with an ethanolic solution of PVP (p. 133, last paragraph). The granulate was obtained by passing it through an 18 mesh screen and drying. It is noted that Eudragit S100 is known to be a copolymer of methacrylic acid and methyl methacrylate (see applicant's response of 10/10/03, evidence document, page 1 of 2). It is also noted that the Methocel substance is hydroxypropylmethylcellulose, and 18 mesh screen has 1 mm (1000 micron) size holes.

The explicit and specific teachings by Gai et al. therefore anticipate the above noted claims. For clarity, the following further analysis and comparison are provided.

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Dimension; modified release; Li salt content; in vitro dissolution profile

Claim 1 requires 200-2000 μm microgranules. Gai et al. obtained their granules by passing the granules through an 18 mesh screen, which would have given them at the most 1000 μm microgranules as the largest sized microgranules.

Claim 1 requires at least a partial or completely modified release. Gai et al. used the same type of modifying coating material (Eudragit S100 and Methocel) as applicant. Compare with applicant's claims 6 and 8.

Claim 1 requires at least 500 mg/g of lithium salt content. The lithium salt content of Gai's microgranules is 68.5 wt% and 82.2 wt%. Such percentages equal to greater than 500 mg/g content.

Claim 1 requires "an in vitro dissolution profile that make it suitable for once-a-day administration." Note that claim 1 does not specify the dissolution protocol. Gai et al. used the USP paddle apparatus, which is different from the basket apparatus used by applicant in the *specification* (e.g., p. 5, line 33). Gai et al. specify the temperature, stirring rate, volume of the dissolution medium, and type of dissolution medium (p. 133, second full paragraph). Gai's figures 1 and 2 show the dissolution profile for various dissolution media. The hydrophilic

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formulation shows about 40% dissolution after 8 hours in the simulated intestinal fluid and simulated gastric fluid. The lipid formulation shows about 40% dissolution after 8 hours in the simulated intestinal fluid. It is the Examiner's position that such dissolution profile meets the claimed requirement in applicant's claim 1 and claims dependent thereon.

Claim 2: up to 1000 mg/dose Li carbonate

As discussed previously, the dose features fails to further define the formulation per se. Therefore, this feature is met by Gai et al.

Claim 9

Claim 9 recites in part, "including conventional release granules and modified release granules, in any proportion." The Examiner shall read and interpret the claim to the broadest extent that is reasonable during the examination process, and shall read "in any proportion" to include 0 proportion, i.e. 0% conventional granules. Such a feature is met by Gai's microgranules.

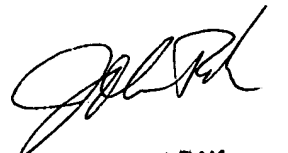
Claim 3 is objected to as being dependent on a rejected base claim, but would be allowable, pending a search update at the time of the next Office Action, if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machines is (703)

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner John Pak whose telephone number is (703) 308-4538. **Effective February 3, 2004, Examiner Pak's telephone number will change to (571)272-0620.** The Examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Mr. Thurman Page, can be reached on (703) 308-2927. Effective February 3, 2004, SPE Page's telephone number will change to (571)272-0602.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.



**JOHN PAK
PRIMARY EXAMINER
GROUP 1600**